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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
MARSCHEL, ARDIN H

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 09/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	**Application No.** 10/677,402	**Applicant(s)** GULATI, SANDEEP	
	Examiner Ardin Marschel	**Art Unit** 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2004*.
2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.
4a) Of the above claim(s) *6-10* is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1-5 and 11-20* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☐ All b)☐ Some * c)☐ None of:
1.☐ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group I (now claims 1-5 and 11-20) in the reply filed on 7/6/04 is acknowledged. The traversal is on the ground(s) that claims 1 and 6 are related via a Chart showing relatednesses on page 8 of said reply and that the inventions of Group I and II are capable of use together, have similar modes of operation, functions, and effects. This is not found persuasive because firstly it is clear from said Chart that the first and second determination units of Group II are not present in the Group I invention which instead utilizes what is clearly a single set of signals processed in the first two upper blocks showing steps within Group I practice. Secondly, these differences in units vs. a signal set determination are not similar modes of operation and functions due to being different and distinct and thus are also not capable of being used together. Thirdly, the effects are different and distinct because it would be expected that different and distinct steps or means of signal analysis would correspond to different and distinct effects resultant therefrom due to analyzing different and distinct parameters within a biological sample. Fourthly, applicants argue that both Groups utilize tessellation as a similarity. In response a single practice being shared between multiply distinct methods as discussed above is insufficient to support the inventions as being indistinct. Lastly, these differences and distinctnesses remain fully supportive of the undue search burden that would be required by searching these Groups together thus supporting maintaining of the restriction requirement.

The requirement is still deemed proper and is therefore made FINAL.

LACK OF SCOPE OF ENABLEMENT

Claims 1, 2, and 11-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methodology which requires the practice of some type of interferometry to amplify signals associated with the biological sample, does not reasonably provide enablement for generic processing to amplify such signals as, for example, is set forth in claim 1, lines 8-9. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below.

It is noted that instant claim 1 is directed to the processing of signals from a biological sample which includes intensities both greater and less than the signals associated with noise with amplification of those signals having an intensity lower than signals associated with noise. Marshall (P/N 5,236,826) and Macovski (P/N 4,686,695) are herein cited as describing the problematic situation of noise obscuring biological signals from solid material samples as also instantly claimed as the source of such signals. Macovski at column 1, line 60, through column 2, line 38, describes biological signal generating systems with explicit discussion of low intensity signals being obscured due to noise. In the abstract, Marshall directs the signal production to correlation with the amount of analyte which is the subject matter of the instant claims directed to determination of specific constituents within a biological sample as in the last 3 lines of instant claim 1. Noise is cited as interfering, especially with a weak signal, in such assays as discussed in Marshall in column 7, lines 40-45. These references attempt to solve the noise problems by suppressing the noise producing aspects of the assays and maximizing desired signal strength, but do not indicate what would amplify the desired signals which are less than the noise signal intensity as instantly claimed. Consideration of the instant disclosure as filed reveals that the amplification of desired signals which have an intensity that is less than noise signals is only described regarding some type of interferometry technique. It is noted that resonance practice, however, is the actual practice of interferometry which is at the basis of the signal amplification practice as instantly disclosed where resonance is well known constructive interferometry. See, for example, the specification on page 9, lines 9-24, wherein the desired signals are produced via convergence (constructive interference). No other processing of signals methodology has been seen as filed and thus, this scope of enablement rejection is reasonably supported as to undue experimentation to amplify such signals that are less than the noise due to the above art references describing dealing with noise by either noise suppression or desired signal enhancement but without setting forth signal amplification as known in the art thus making it unpredictable to amplify signals out of the noise without specific guidance therefor. Only the interferometry type of amplification is instantly set forth thus making only claims limited to this practice enabled and not generic claims that are not so limited.

OBVIOUSNESS-TYPE DOUBLE PATENTING

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 11, and 15-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims

1-4, 25, 26, and 30 of U.S. Patent No. 6,142,681. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to tessellating the output pattern from a biological sample and utilizing resonance, a type of interferometry, to interpret the pattern for analyzing the sample for constituents therein. The amplification of signals both lesser and greater than the noise is expected from the practice of both sets of claims due to both utilizing the resonance methodology for signal analysis.

Claims 1-5, 11, and 15-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 and 24 of U.S. Patent No. 6,671,625. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to tessellating the output pattern from a biological sample and utilizing resonance, a type of interferometry, to interpret the pattern for analyzing the sample for constituents therein. The amplification of signals both lesser and greater than the noise is expected from the practice of both sets of claims due to both utilizing the resonance methodology for signal analysis.

Claims 1-5, 11, and 15-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 and 10-22 and 24 of U.S. Patent No. 6,780,589. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to tessellating the output pattern from a biological sample and utilizing resonance, a type of interferometry, to interpret the pattern for analyzing the sample for constituents therein. The amplification of signals both lesser and greater than the noise is expected from the practice of both sets of claims due to both utilizing the resonance methodology for signal analysis.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 17, 2004

Ardin H. Marschel 9/17/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER